REMARKS/ARGUMENTS

Status of the Claims

Claims 1, 5, 6, 9-11, 13, 14, 19, 20 and 22-28 are pending. Claims 22-26 are withdrawn from consideration. Claims 1, 5, 6, 9-11, 13, 14, 19, 20, 27 and 28 are rejected.

Claim amendments

Claims 1, 13, 14 , 19 and 27 are amended herein. No new matter is added to these claims. Claims 1, 13, 14, 19 and 27 are amended to overcome the 35 U.S.C. §112 first paragraph rejections. In general, amended claims 1 and 13 recite three generating steps, where one generating step is drawn to generating at least one immunological composition directed against at least one of the first peptide with specific SEQ ID NOs. Similarly, the remaining two generating steps are drawn to generating at least one immunological composition directed against at least one of second peptide with specific SEQ ID NOs and against at least one of third peptide with specific SEQ ID NOs, respectively. Further, the contacting steps in both these claims are amended to recite the step of contacting aliquots of the sample separately with each of the above mentioned at least one immunological composition. Furthermore, the quantity of the bound immunological composition in each aliquot is measured and the type of the bound immunological composition in each aliquot is compared to determine the concentration of at least one of the active or inactive form of the urokinase in the sample. The total of

the concentration of the active and inactive forms of urokinase represents the total urokinase concentration in the sample.

Similarly, the kit in claim 14 is amended to recite three different immunological composition(s) as discussed supra. The amendment discussed herein are supported by the disclosure in paragraphs [0022]-[0032], [0034]-[0035], [0038]-[0059] and Examples I-III in Applicant's specification. Additionally, the reference to functionally equivalent peptides containing amino acid substitutions is deleted from claims 1, 13, 14, 18, 19 and 27.

The 35 U.S.C. §112, First Paragraph Rejections

Claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 remain rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

On page 3 of the Office Action, the Examiner states that the Applicant was not in possession of "functionally equivalent peptide(s) containing an amino acid substitutions with a difference in the hydropathic index value of ± 1-2". While elaborating on this on page 4 of the Office Action, the Examiner states that the substitutions that conserve the hydropathic index values of the amino acid being substituted and its replacement are precisely the kinds of substitutions that can occur in homologues of urokinase. The Examiner further states that the instant application teaches that the affinities of the immunological compositions for peptides having the recited

sequences must be "substantially higher" than their affinities for homologues of other species.

Claims 1, 13, 14, 19 and 27 are amended as discussed supra to remove reference of the functionally equivalent peptides containing amino acid substitutions with a difference in the hydropathic index value of ± 1-2. Hence, the claims comply with the written description requirement since the rest of that amended claims are supported by the disclosure in paragraphs [0022]-[0032], [0034]-[0035], [0038]-[0059] and Examples I-III in Applicant's specification Accordingly, based on the amendments and remarks presented herein, Applicant respectfully requests the withdrawal of rejection of claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 under 35 U.S.C. §112, first paragraph.

Claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 are rejected under 35 U.S.C. §112, first paragraph for lack of enablement. Applicant respectfully traverses this rejection.

The Examiner states that the specification while enabling for the use of antibodies specific for the particularly recited SEQ ID NOs, does not reasonably provide enablement for use of antibodies specific for the full genus of peptides including those that are "functionally equivalent peptide(s) containing an amino acid substitutions with a difference in the hydropathic index value of ± 1-2". The Examiner states that limiting the claim to the functionally equivalent peptides as discussed herein would not be enabled although para 0031 in the instant specification teaches that doing so might result in a peptide having similar biological activity.

The Examiner states that undue experimentation would be required to produce the antibodies directed against the "functionally equivalent peptides" that could detect urokinase since one would have to immunize a different host animal with each of the peptides encompassed by the genus and then characterize the binding specificity of the antibodies thus produced. According to the Examiner, this amounts to undue experimentation since binding specificity of any antibody is dependent on factors besides the hydrophobicity of the peptide/epitope that the antibody binds to.

Claims 1, 13, 14, 19 and 27 are amended as discussed supra to remove reference of the functionally equivalent peptides containing amino acid substitutions with a difference in the hydropathic index value of ± 1-2. Hence, the claims comply with the written description requirement since the rest of the amended claims are supported by the disclosure in paragraphs [0022]-[0032], [0034]-[0035], [0038]-[0059] and Examples I-III in Applicant's specification. Accordingly, based on the amendments and remarks presented herein, Applicant respectfully requests the withdrawal of rejection of claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 under 35 U.S.C. §112, first paragraph.

Claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

The Examiner states that Applicant has entered new matter in the "generating" step of claims 1 and 13 and in the "immunological compositions" paragraph of claim 14. Specifically, the Examiner states that claim 1 can be read as "generating at least

one immunological composition against at least one of a first peptidc....a second peptide...and a third peptide." This can be understood to mean that "at least one immunological composition is generated against a mixture of first peptide...a second peptide and a third peptide." The Examiner states that no such immunological composition is disclosed. The same considerations are applied to claims 13-14.

The Examiner states that the Applicant must indicate that one is generating at least one immunological composition against against each one of the listed groups of a first peptidc, a second peptide and a third peptide. The Examiner further suggests that applicant recite three distinct, indented "generating steps" in claims 1 and 13 and then recite three distinct, indented "immunological compositions" in claim 14 in order to comply with 37 CFR 1.75(i).

Claims 1, 13 and 14 are amended as discussed supra so that either the method (claims 1 and 13) and the kit (claim 14) recite three different immunological compositions. The instant specification discloses using at least one immunological composition directed against the first peptide, at least one immunological composition directed against the second peptide and at least one immunological composition directed against the third peptide. The method or the kit may further comprise at least one immunological composition directed against the fourth peptide. Further, each of these immunological compositions is added to different aliquots of the sample and the quantity of immunological composition bound in each of the aliquots of the sample is measured.

Additionally, the type of immunological composition bound is also compared to determinc the concentration of active or inactive form of urokinase. This is

because each immunological composition will bind at least one of said active or inactive forms of urokinase and is therefore indicative of the concentration of the form that it is bound to. Then the concentration of the active and inactive form thus determined is added to get the total urokinase concentration in the sample. Thus, the methods and the kits disclosed and claimed herein should comprise immunological compositions directed against each of these peptides.

Applicant submits that the amended claims are clearly supported by the teachings and disclosure in paragraphs [0022]-[0032], [0034]-[0035], [0038]-[0059] and Examples I-III in Applicant's specification. Thus, these claims comply with the written description requirement. Accordingly, based on the claim amendments and above-discussed remarks, Applicant respectfully requests the withdrawal of rejections of claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 under 35 U.S.C. §112, first paragraph.

Claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

The Examiner states that the Applicant has entered new matter in the "contacting" step of claims 1 and 13-14. Specifically, the Examiner states that the claims as they are written require "contacting said sample with each of said at least one immunological compositions". This according to the Examiner can be read to mean that all three of the "at least one immunological compositions" are added together to the same sample aliquot which is not the same as disclosed in the instant specification. The Examiner

states that the original claims and the disclosure required that each of the three "at least one immunological compositions" be separately added to different sample aliquots.

Applicant respectfully points out that claim 14 is drawn to a kit and not to a method for determining total urokinase concentration. Hence, there is no "contacting step" in this claim. However, the contacting step in claims 1 and 13 are amended as discussed supra. The amended method recites contacting aliquots of the sample separately with each of the at least one immunological composition. In other words, each of the 3 "at least one immunological compositions" is added separately to different sample aliquots. As discussed supra, this amendment is supported by the disclosure in paragraphs [0022]-[0032], [0034]-[0035], [0038]-[0059] and Examples I-III in Applicant's specification. Hence, claims 1 and 13 comply with the written description requirement. Accordingly, based on this amendment and remarks, Applicant respectfully requests withdrawal of rejection of claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 under 35 U.S.C. §112, first paragraph.

Claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

The Examiner states that Applicant has not taught how one is to use "at least one immunological composition" generated against mixture of first peptide, second peptide and a third peptide. Specifically, the Examiner states that claim 1 reads as "generating at least one immunological composition against at least one of a first peptide, a second peptide and a third peptide. This according to the Examiner can be understood to mean that "at least

one immunological composition" is generated against mixture of a first peptide, a second peptide and a third peptide". The Examiner states that Applicant has not disclosed how to use such an immunological composition.

The Examiner states that to the contrary, the Applicant has indicated that one must use "at least one immunological composition" generated separately against each one of the listed groups of first peptide, second peptide and a third peptide. Thus, 3 such compositions would be necessary to arrive at the calculation of "total concentration" as recited in the concluding paragraph of claim 1. The same considerations are applied to claim 13-14.

Claims 1, 13 and 14 are amended as discussed supra so that either the method (claims 1 and 13) and the kit (claim 14) recite three different immunological compositions. The instant specification discloses using at least one immunological composition directed against the first peptide, at least one immunological composition directed against the second peptide and at least one immunological composition directed against the third peptide. The method or the kit may further comprise at least one immunological composition directed against the fourth peptide. Further, each of these immunological compositions is added to different aliquots of the sample and the quantity of immunological composition bound in each of the aliquots of the sample is measured.

Additionally, the type of immunological composition bound is also compared to determine the concentration of active or inactive form of urokinase. This is because each of the immunological composition will bind at least one of said active or inactive forms of urokinase and is therefore indicative of the concentration of the form that it

is bound to. Then the concentration of the active and inactive form thus determined is added to obtain the total urokinase concentration in the sample. Thus, the methods and the kits disclosed and claimed herein should comprise immunological compositions directed against each of these peptides.

Applicant submits that the amended claims are clearly supported by the teachings and disclosure in paragraphs [0022]-[0032], [0034]-[0035], [0038]-[0059] and Examples I-III in Applicant's specification. Thus, the amended claims are commensurate with the scope of the instant invention. Accordingly, based on the claim amendments and above-discussed remarks, Applicant respectfully requests the withdrawal of rejections of claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 under 35 U.S.C. §112, first paragraph.

Claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

The Examiner states that Applicant has not disclosed how "to measure the quantity and type of each of said at least one immunological compositions bound in said sample' when all three of the "at least one immunological compositions" are added together to the same sample aliquot. The Examiner further states that unless each of the three "at least one immunological compositions" are separately added to different sample aliquots, there is no way in which one can measure the quantity and type of each of said at least one immunological compositions bound in said sample.

Claims 1 and 13 are amended as discussed supra. These methods recite three separate generation of immunological compositions. Further, the methods also recite contacting aliquots of the sample separately with each of the immunological compositions. Furthermore, the concentration of the active and inactive forms of urokinase is determined by measuring the type of the immunological composition bound in each of the aliquots combined with the comparison of the type of the immunological composition bound in the aliquot. Thus, the claims now recite adding the three immunological compositions separately to different sample aliquots to measure the quantity and type of each of said at least one immunological compositions bound in said sample. This amendment is supported by the disclosure in paragraphs [0022]-[0032], [0034]-[0035], [0038]-[0059] and Examples I-III in Applicant's specification. Thus, the amended claims are commensurate with the scope of the instant invention. Accordingly, based on the claim amendments and above-discussed remarks, Applicant respectfully requests the withdrawal of rejections of claims 1, 5, 6, 9-11, 13-14, 19-20 and 27-28 under 35 U.S.C. §112, first paragraph.

This is intended to be a complete response to the Offiee Action mailed January 09, 2008. Applicant submits that the pending claims are in condition for allowanee. If any issues remain outstanding, please telephone the undersigned attorney of reeord for immediate resolution.

Respectfully submitted,

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